1645

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Application
Serial No.: 10/083,476

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Group Art Unit: 1645

Examiner: Devi, S.J.N.

Title: MODIFICATION OF BIOASSAYS FOR DETECTION OF ANTIGENS CHARACTERISTIC OF BACTERIA THAT ARE CAUSATIVE OF EAR AND RESPIRATORY INFECTIONS TO ELIMINATE FALSE POSITIVE RESULTS CAUSED BY NASOPHARYNGEAL COLONIZATION OF CHILDREN

RESPONSE TO OFFICE ACTION MAILED OCTOBER 1, 2003

Applicants hereby provisionally elect, with traverse, the invention covered by Claims 1-8 of this application for further prosecution.

Applicants traverse the restriction requirement as improper for all of the following reasons:

1. The requirement, as made, fails to show that Claim 9, designated as "Invention II" in the action is patentably distinct from Claims 1-8 (dubbed "Invention I" in the action). Instead it arbitrarily states that the "method steps/parameters" are distinct from one another and the "reagents or materials" are different.

2. In fact, the single method step in each instance consists of allowing sample to flow along a preprepared immunochromatographic ("ICT") test strip to a "capture" zone containing predeposited labelled antibodies, allowing the sample and test strip to rest for about 15-20 minutes and observing the result.

The sole difference between "Invention I" and "Invention II" consists in the preliminary preparation of the ICT test strip. In the claims dubbed "Invention I", the concentration of labelled antibody immovably fixed at the capture line of the strip is reduced. In the claim dubbed "Invention II", the concentration of labelled antibodies at the capture line retains its original concentration. However, one or more pre-capture or "scrub" lines consisting of the same antibodies in unlabelled form and lowered concentration is striped across the ICT strip in the sample flow path. This line or combination of lines has the object of tying up an amount of antigen in the sample that is attributable to the degree of bacterial colonization in otherwise healthy patients, so that the antigen in the sample that reaches the labelled capture line antibodies reflects only patient disease.

It is hard to see how these variants in ICT test strip preparation, both having the object of distinguishing samples obtained from diseased patients from samples obtained from healthy but colonized patients (thereby avoiding false positive tests and inadvertent medication of healthy patients) *can* be patentably distinct and no evidence to that effect has been provided.

3. The subject matter here is *not* divergent; it involves *the same* reagents in each case; only the concentrations of reagents are varied. Moreover, insofar as the end user of the test is concerned, it is performed *identically* regardless of how the test strip is prepared.

4. The object of both test variations is to *reduce* the incidence of false positive results obtained in patient populations where many otherwise healthy individuals are bacterially colonized but are healthy.

5. It seems almost intuitive that the same field of search *must* require investigation in the instance of both "Invention I" and "Invention II". The Examiner has not discharged the burden of showing the contrary.

CONCLUSION

Withdrawal of the requirement for restriction is courteously requested in all the circumstances.

Respectfully submitted,

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41

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If you have any questions, please contact Cynthia Streater at 703-306-5430 or Eleanor Kurtz at 703-308-3642.

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